## Remarks

Claims 18 and 19 have both been amended by the introduction of the term "non-fibrous". Thus, the two claims as amended now specify that the solid carrier they refer to is "non-fibrous". The basis for this amendment can be found at page 6 lines 19-20 of the application as filed. Claims 18, 19, 31 and 34 have been amended to more distinctly claim what Applicants regard as the invention by deleting the term "about". Claim 40 has been amended by inserting "(a)" and "(b)" before the terms "a derivatised cellulose" and "an edible oil" respectively. In addition, a semicolon has been placed after the term "hydroxy-ethyl-cellulose". No new matter has been added by way of any claim amendments. A marked-up copy of the amended claims is included herewith.

**A.** Claims 18-24, 26 -28 and 31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen *et al.* (WO-A-95/28850) in view of Jacobsen *et al.* (WO-A-92/12645). In essence, the Examiner's argument is that one of skill in the art would have a reasonable expectation of success at making a phytase-containing granulate of 10,000 FTU/g, as referred to by Nielson *et al.*, comprising 2 to 40% cellulose (an edible carbohydrate), because Jacobsen *et al* shows that enzyme-containing granulates wherein the granulates contain up to 40% cellulose can be used in animal feeds.

Jacobsen *et al.* discloses a T-granulate which is coated with a coating agent comprising a high melting fat or wax as a component of a mixture which is proposed for use as a fodder if the mixture is steam treated and subsequently palletised. At page 2 lines 14 and 15, Jacobsen *et al.* define a T-granulate as:

> *"a granulate produced according to US-A-4,106,991, i.e. a granulate containing 2 to 40% of finely divided cellulose fibers."* [Emphasis added].

It can therefore be seen that Jacobsen *et al.* relates only to granulates in which a carrier comprising 2 to 40% of finely divided cellulose fibers is used. If follows that Jacobsen *et al.* relates only to granulates wherein the carrier has to be fibrous in nature. By contrast, claims 18 and 19 of the present application have now been amended so that they are directed only to granulates (and compositions comprising such granulates) in which the carrier is non-fibrous. As stated above, page 6 lines 19-20 of the application as filed describes how non-fibrous carriers allow for easier granulation because fibrous materials can prevent granulation by extrusion.

Nielson *et al.* deals with granulates which do not comprise an edible carbohydrate polymer carrier. It is therefore submitted that a combination of Nielson *et al.* and Jacobsen *et al.* could not have been combined in order to achieve a granulate falling within the scope of claims 18 and 19 as amended. Even if one of skill in the art had combined the teaching of Nielsen *et al.* with the teaching of a fibrous carrier-based granulate as taught by Jacobsen *et al.*, that skilled person could still not have achieved a granulate comprising an edible carbohydrate polymer wherein the carrier is non-fibrous: the two documents could only have been combined to arrive at a fibrous carrier-based granulate.

On the basis of these arguments, it is submitted that claims 18 and 19 as amended are indeed patentable over Nielson *et al.* in view of Jacobsen *et al.* The remaining claims are either dependent on claims 18 or 19 or refer back to those claims (and thus incorporate all of the features of claims 18 and 19) and therefore, for the reasons set out above, it is submitted that these claims are patentable too.

During an interview on October 31, 2002 between the Examiner and Alison Baldwin (an attorney of record), the Examiner suggested that additional evidence be introduced as to

why the use of non-fibrous carriers would not have been expected, i.e. why such carriers would not have been obvious. No such secondary considerations need be submitted at the present time because Applicants contend the Examiner has not established a *prima facie* case of obviousness, i.e. the combination of Nielson *et al.* and Jacobson *et al.* do not teach or suggest all the limitations of the claims. Specifically, even if the two prior art documents relied on by the Examiner are combined, it is still not possible to achieve a granulate falling within the scope of the claims as amended. Jacobsen *et al.* refers only to fibrous carriers and Neilson *et al.* refers only to non-carbohydrate carriers. Thus, the art relied on by the Examiner cannot be combined to achieve a non-fibrous carbohydrate polymer-based carrier containing granulate and, on that basis, the claims cannot be obvious; at best, the two references in combination, as mentioned above, suggest a fibrous carrier-based granulate. In summary, it is submitted that Applicants have dealt fully with the Examiner's objections under 35 U.S.C. 103(a) insofar as they relate to claims 18 and 19. Withdrawal of the obviousness rejection is therefore respectfully requested.

**B.** Claims 19, 21, 22, 25 and 39 under 35 U.S.C. 103(a) stand rejected as being unpatentable over Nielsen *et al.* (WO-A-95/28850) in view of Rokey *et al.* (US-A-5,480,673). Rokey *et al.* teaches an extrusion process for the production of animal feeds having high soluble protein contents wherein respective starch-bearing and proteinaceous ingredient fractions are differentially processed so as to obtain an extruded final product containing soluble protein. Applicants submit that even if one of skill in the art were to combine that teaching with the teaching set out in Nielson *et al.*, he/she would still not achieve a granulate falling within the scope of the claims. Specifically, Rokey *et al.* relates to an extrusion process for the production of animal feeds having a high soluble

protein content wherein any starch present in the resulting animal feed is cooked. This can be seen in the "Summary of the invention" section of Rokey *et al.* at column 2, lines 27 to 29. That passage refers to:

> *"....an extruded edible body including a matrix which comprises extrusion cooked starch-bearing grain."* [Emphasis added].

Therefore, when the teaching of Rokey *et al.* is considered in context and as a whole, it can be seen that any attempt by one of skill in the art to combine Rokey *et al.* with Nielson *et al.*, in the manner the Examiner suggests, results in a final product that is cooked. That is of course highly significant in the context of the present application. The claims of the present application are directed to a phytase-containing granulate which contains active phytase. This is set out explicitly in the first line of claim 19 which refers to:

> *"A granulate having a phytase activity of at least 6000 FTU per gram....."* [Emphasis added].

Thus, the processing used to form the granulate set out in the claims of the present application necessarily excludes processing techniques wherein the granulate is cooked. Clearly, any cooking would lead to inactivation of any enzyme present and no phytase activity would be observed.

By contrast, any attempt to combine the teaching of Nielson *et al.* with Rokey *et al.* would have to include the extrusion process set out in the latter of those two documents which, because the granulate is cooked, would inevitably result in a granulate with no enzyme activity. In other words, a hypothetical granulate produced according to a combination of Nielson *et al.* and Rokey *et al.* would be a cooked extruded feed in which all the enzyme present, for example phytase, would be inactive. That sort of granulate falls outside the scope of the instant claims, which are directed to a granulate which has a phytase activity of at least 6,000 FTU per gram.

During the interview of October 31, 2002, the Examiner suggested that evidence be filed in support of this view, because phytases are well-known to be fairly heat tolerant. Applicants submit herewith Rodriguez *et al.*, *Biochem. and Biophys. Res. Comm.* 268, 373-378, 2000. Rodriguez *et al.* asserts the notion that phytases are generally not thermostable, at least to the extent that would be required for them to remain active in the Rokey process. Indeed, Rodriguez *et al*, teaches at page 373, right hand column, lines 7-9:

> *"their [i.e. phytases] constraints of thermostability do not allow these enzymes to sustain the heat denaturation of regular feed pelleting."*

In particular, Figures 3 and 4 of Rodriguez *et al.* show that phytase activity drops off significantly at temperatures over 60°C. However, Rokey refers to a maximum cooking temperature of up to 300°F, i.e. 149°C (see column 4 at lines 47 and 48), a temperature at which phytase activity would seem to be negligible according to Rodriguez *et al.* Although Rodriguez *et al.* refers to one particular thermostable enzyme (from *A. fumigatus*, the subject of this paper), this is not the norm and, generally speaking, phytases are not sufficiently thermostable to survive the temperatures used during the heat pelleting described in Rokey. For the above reasons, it is submitted that the granulate of the present claims is indeed patentable over a combination of Nielson et al. and Rokey et al and withdrawal of the obviousness rejection is respectfully requested.

Allowance of the claims and passage of the case to issue are respectfully solicited. Should the Examiner believe a discussion of this matter would be helpful, she is invited to telephone the undersigned at (312)-913-0001.

Respectfully submitted,

By: Stephen H. Docter

Stephen H. Docter
Reg. No. 44,659

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McDONNELL BOEHNEN
HULBERT & BERGHOFF
300 South Wacker Drive, 32nd Floor
Chicago, Illinois 60606
(312) 913-0001

**Marked-Up Copy of Claims for U.S.S.N. 09/089,871**

Claims 18, 19, 31, 34 and 40 are amended as follows.

18. (Five Times Amended) A phytase-containing granulate prepared by a process comprising the steps of:

(a) providing a non-fibrous solid carrier comprising at least ~~about~~ 15% (w/w) of an edible carbohydrate polymer;

(b) providing an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid; and

(c) mixing the solid carrier and the aqueous liquid to form a granulate having a phytase activity of at least 6000 FTU per gram.

19. (Four Times Amended) A granulate having a phytase activity of at least 6000 FTU per gram comprising dried granules formed from an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid and a non-fibrous solid carrier which comprises at least ~~about~~ 15% (w/w) of an edible carbohydrate polymer.

31. (Twice Amended) A composition comprising:

(c) a granulate according to claim 18;

(d) a phytase-containing granulate with an activity of at least ~~about~~ 6,000 FTU/g; or both a granulate according to (a) and a phytase-containing granulate according to (b).

34. (Amended) A composition according to claim 31, wherein said composition comprises pellets that comprise one or more feed substance(s) or ingredient(s) mixed with a granulate that comprises dried granules formed from a phytase and a solid carrier which comprises at least ~~about~~ 15% (w/w) of an edible carbohydrate polymer.

40. (Amended) A granulate according to claim 22 comprising: (a) a derivatised cellulose selected from the group consisting of hydroxy-propyl-methyl-cellulose, carboxy-methyl-cellulose and hydroxy-ethyl-cellulose; and (b) an edible oil selected from the group consisting of soy oil and canola oil.